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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/860,844	09/29/1997	SUSAN WEININGER	GP-100C1	9470

7590 11/05/2002

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[REDACTED] EXAMINER

MARSCHEL, ARDIN H

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1631

DATE MAILED: 11/05/2002

*Qg*

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>08/860,844</b>	Applicant(s) <b>Weininger et al.</b>
Examiner <b>Ardin Marschel</b>	Art Unit <b>1631</b>

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Aug 26, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 28, 29, 49, and 52-61 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 28, 49, 52-55, and 59-61 is/are rejected.

7)  Claim(s) 29 and 56-58 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on Aug. 26, 2002 is/are  accepted or  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

Applicants' arguments, filed 8/26/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are reiterated. They constitute the complete set presently being applied to the instant application.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to detection methods whereas, in contrast, only prophylactic, therapeutic, and assembly methods are set forth in the presently pending claims. No detection methods are claimed.

Claims 59-61 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The downregulation in claim 59 is NEW MATTER as this suggests gene expression effects beyond merely less affinity of the recognition units versus wildtype molecules. The citations pointed by applicants merely cite less binding affinity and do not further suggest gene expression effects as the word "downregulated" in claim 59 does which therefore contains NEW MATTER. This rejection is necessitated by amendment.

Claims 60 and 61 contain NEW MATTER due to the generic 4 and 8 nucleotides limitations. The written basis as pointed to by applicants on pages 31, 52, and 53 only cite specific TATA segments and not the concept of 4 or 8 nucleotide segments from any nucleic acid recognition unit as now claimed in claims 60 and 61. Therefore these limitations are NEW MATTER. This rejection is necessitated by amendment.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 28, 52-54, 60, and 61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Frankel et al. (P/N 5,674,980).

This rejection is reiterated and maintained from the previous office action, mailed 2/25/02, and as necessitated by amendment regarding newly submitted claims. This rejection is argued regarding the limitation in claim 28 directed to a plurality of nucleic acid recognition units being present in the TBA assembly therein utilized as being distinct from the reference. In response Frankel et al. was previously cited in the office action, mailed 8/15/00 (Paper No. 17), as describing a fusion protein between tat and E2 in column 18, line 31, through column 19, line 20. A review of that citation reveals that column 18, lines 35-41, describes the E2 region in said fusion protein as containing both positive and negative acting transcriptional regulators. This is a plurality of double stranded nucleic acid molecule recognition units thus still supporting this rejection contrary to the argument of applicants. Applicants then argue that the system of Frankel et al. is designed for a different purpose from that of the instant invention. In response it is not seen what bearing that the reason for design of an assembly is regarding this rejection. The instant claim 28 lacks any design step limitation(s) and therefore this argument is moot as being directed to a practice which is not a claim step per se.

Claims 49 and 55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Essigmann et al. (P/N 5,882,941).

This rejection is maintained and reiterated from the previous office action, mailed 2/25/02, and as necessitated by amendment regarding newly added claim 55. This rejection is argued regarding the content of non-nucleic acid recognition units in the reference. This is non-persuasive because a review of the sections of the reference previously pointed to reveals that at column 7, lines 41-55, two agents apparently are cited which both act at or on a genomic lesion site thus supporting this rejection as well as the rejection of newly added claim 55 as genomic attraction is clearly a nuclear localization signal.

Claims 29 and 56-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE

STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

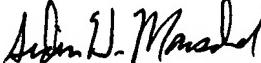
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 1, 2002



ARDIN H. MARSCHEL  
PRIMARY EXAMINER